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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,079	02/05/2004	William Jackson Devlin SR.	DCS-9119B	6037

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EXAMINER	
GAKH, YELENA G	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,079	DEVLIN ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/27/04, 11/08/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification and Drawings

1. The specification and/or Figure 1 are objected to since there is a discrepancy between the description of Figure 1 in the specification and the drawing itself. The specification discloses that Figure 1 shows the elements of conventional automatic chemical analyzer 10, which according to the drawing includes element 50. The specification further discloses element 50 as inventive. Either the specification should be corrected by withdrawing the term "conventional" from describing automatic analyzer 10, or the drawing should be changed so that number 10 points exclusively to the parts of the conventional analyzer, excluding part 50.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 7-8 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not disclose bar codes with such interactive capabilities as recited in the claims, since establishing the period of time that the second sample aliquot is retained in the storage compartment after tests in the first sample aliquot are completed is variable depending on the test performed on the first sample aliquot. There is no way for a routineer in the art to perform the method recited in these claims, since the specification does not provide an adequate disclosures for such variable interactive bar code, with bar code usually comprising a set of fixed instructions. The only interactive

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "providing indicia on the sample container to indicate a period of time". What type of indicia and which period of time are meant in his step? Is this the time when the sample is deposited into the sample container? How is this time related to the time of performing first tests of the patient's sample? Is the indicia provided after all initial tests were performed? Further, claim 1 recites the steps, the sequence of which is not clear. Where is the first aliquot portion of the patient's specimen is deposited after being extracted from the container? Where is the first aliquot contained while the second aliquot is extracted?

Claim 3 is totally unclear. What does it mean, "the tests to be performed upon a patient's specimen are examined to ascertain the period of time the patient's specimen is to be retained in storage"? The examiner cannot interpret this claim in any meaningful sense.

From claims 7 and 8 it is not apparent, what type of bar code indicia can contain "instructions that establish the period of time that the second sample aliquot is retained in the storage compartment after tests on the first sample aliquot are completed"? Bar code is attached to the sample container, from which both aliquots are taking. How can bar code provide instructions, which seems to be interactive, since they depend on when the first aliquot is taken from the sample container? Bar codes do not have capabilities to be interactive.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. **Claims 1-4, 6 and 9-10** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza (US 5,350,564, IDS) in view of Thorne et al. (US 4,678,752, IDS).

Mazza discloses, "the present invention relates to an adaptive, versatile conveyor system for feeding individual sample tubes, cells, *cuvettes*, and the like (hereinafter collectively referred to as "sample tubes") each held in an individual prismatic sample tube carrier, either from associated groups or batches which are taken in regular order, or from a stat sample area taken with priority; identifying the individual sample tubes; conveying and/or temporarily storing the individual sample tubes as required; transferring the individual sample tubes to and from one or more associated analysis modules of the apparatus as appropriate; ***retaining the individual sample tubes in temporary storage while test results are obtained, and returning the individual sample tubes to associated groups in response to an indication that analysis of a particular sample is complete and verified as reliable***. The present invention has particular utility for use in automated chemical analyzers and related equipment for analysis and testing of blood, physiological fluids, and other biological samples" (col. 1, lines 18-38); "the carriers are individually fed to a rotator assembly which provides both for the *reading of a bar code tag on the sample tube* in the carrier, and the rotational orientation of the carrier in a particular presentation" (col. 5, lines 20-24). Sample carriers returned from an analyzer to the loop conveyor are retained thereon, along with incoming samples en route to an analyzer, and priority stat samples which will be received by an analyzer prior to the rank and file samples, until the results of the tests on the sample are confirmed. Thus, the loop conveyor provides a dwell capacity in association with the analyzer. This dwell capacity also allows rank and file samples

to be held in abeyance on the loop conveyor while stat samples traverse the conveyor immediately en route to the analyzer. *In the event the test results are not confirmed, the particular sample may be fed from the loop conveyor back to the analyzer for a second or subsequent testing*" (col. 5, lines 33-43).

"The entire operation of the conveyor is under the control of a dynamic controller so that each discreet action with respect to a sample carrier from the time its sample is identified until the sample test results are verified and the carrier is off loaded is tracked. Thus, test results are easily correlated with a particular sample and patient. Also, the location of each sample on the loop conveyor, and of vacant receptacles, which are available for receipt of a stat or of a rank and file sample, is always recorded. *This feature of the conveyor along with its storage and dwell time feature makes possible the recall to an analyzer module of any particular sample in the event the results of a test are not verified as reliable*. This latter feature is of high importance with stat samples. If the test results for any start sample are not reliable, the sample will be recalled to the analyzer and retested. Only when the test results of each sample are verified will the sample be delivered to the off-loading area" (col. 5, lines 56-68, col. 6, lines 1-6).

Mazza does not specifically indicate that the bar code on the sample container has information on the time period for the sample to be retained at the storage compartment.

Thorne discloses an automatic random access analyzer comprising an environmentally controlled (col. 10, lines 60-67) incubation storage area 18 within the analyzer for storing a plurality of reagent packages comprising reagent solutions, with the packages having barcode labels 46 with the information on expiration date (col. 5, lines 60-68). The reagents are automatically extracted for further use in automated analyzer.

It would have been obvious for any person of ordinary skill in the art to slightly modify Mazza's method by including information on the time period during which the sample can be retained in the storage space fur further analysis the way it is taught by Thorne for the reagents, because the samples are degenerating with time the same way the reagents do and become unacceptable for further analysis. Therefore, it would have been obvious for any person of ordinary skill in the art to discard the samples which were retained in the storage compartment for the period of time exceeding the expiration date (the time period) and to alert the user about such expiration of the time period.

10. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza in view of Thorne, as applied to claims 1-4, 6 and 9-10 above, and further in view of the well known prior art, e.g. Boosalis et al. (US 4,362,698, IDS).

Although Mazza in view of Thorne do not specifically indicate using a protective film (layer, lid, foil, etc.), which can be easily removed or pierced, their use for covering the samples to be analyzed are well known in the art, as disclosed by e.g. Boosalis.

While Boosalis discloses a more complex cover for fluid sample cups, which serves many purposes and contains several layers, including film, adhesive tape, etc., it would have been obvious for anyone of ordinary skill in the art to use any simple cover for sample in Mazza's method, including film, foil, plastic, etc., which is just one layer of Boosalis' cover and which may serve exclusively for protection of the samples and, on the other hand, be easily removed or pierced, because it is a conventional way of protecting samples of biological analytes from contamination during analysis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

09/19/2007

Yelena Gakh

YELENA GAKH
PRIMARY EXAMINER